



# **Digital Pen and Paper**

**Study AC-060A202: CONTROL**  
**Aurélien Thiers**



## Digital Pen & Paper Agenda

- What is the DPP?
- What are the components?
- How is the DPP installed?
- How does the DPP work?
- What are the advantages?
- What are the potential problems?
- Summary

## DPP: What is it?

It is a technology based on the capture of CRF data **whilst you write on the** Case Report Form.

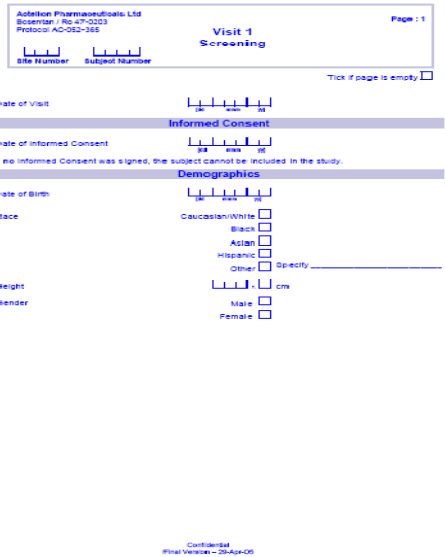


## DPP: What are the components?



Paper + Pen + Digital

## DPP components: The Paper



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Savitari, P.O. 47-0020  
Protocol AC-060-365

Page : 1

Site Number Subject Number

Tick if page is empty ☐

Date of Visit

Informed Consent

Date of Informed Consent

If no Informed Consent was signed, the subject cannot be included in the study.

Demographics

Date of Birth

Race

Caucasian/White ☐  
Black ☐  
Asian ☐  
Hispanic ☐  
Other ☐ Specify \_\_\_\_\_

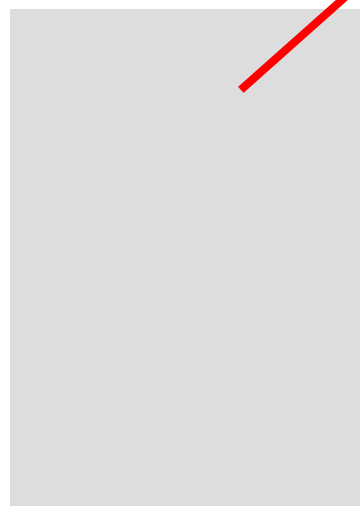
Height

Gender

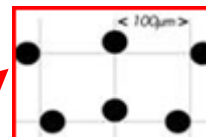
Male ☐  
Female ☐

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Final Version - 20-Apr-05

**Standard form**



**Unique pattern**



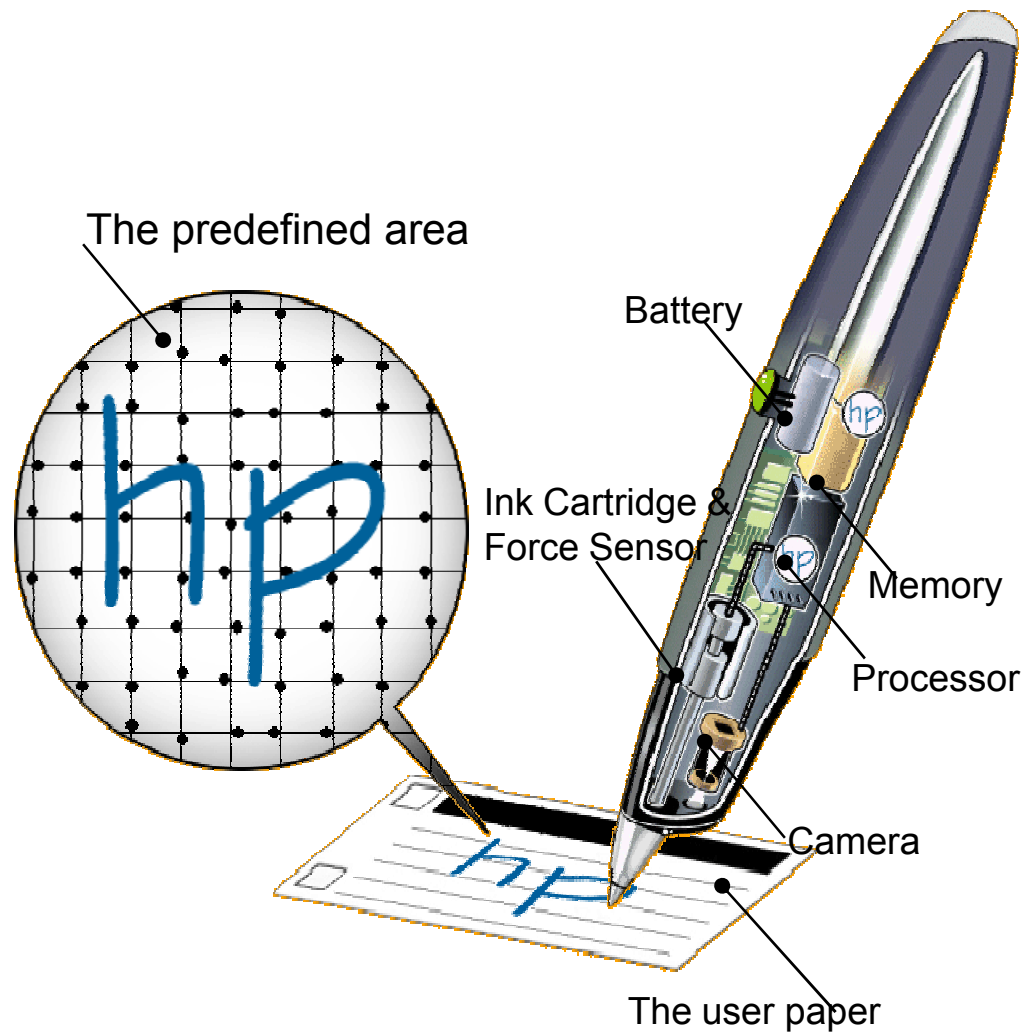
**Small Dots**



**Smart paper forms  
printed on HP  
LaserJet printers**

**The unique pattern enables the pen to record data from the CRF and to **identify the study, subject** and **CRF Page**.**

## DPP components: The Digital Pen



## DPP components: The Digital Pen (cont'd)



## DPP components: The Digital Pen (cont'd)

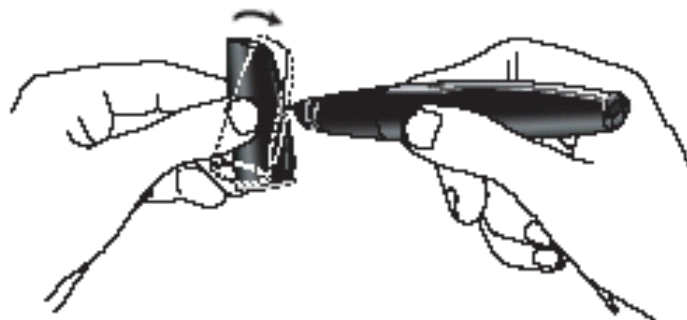
- The digital pen writes like a normal pen but contains a **camera** → each pen stroke is recorded electronically in the pens memory
- **Buzz:**
  - One vibration when the cap is removed
  - More than one vibration when either:
    - Battery is < 10% full
    - Memory is full
- **LEDs:** **Battery = Red** → Battery is empty; **Green** → > 50% full battery  
**Memory = Red** → 1-30% free; **Green** → > 50% memory available



## DPP: Changing the ink

When the ink cartridge in the pen runs out, replace it with one of the refills supplied with your pen. Use the pen's cap to remove the empty ink cartridge.

1. Remove the cap from the pen.
2. Place the ink cartridge tip in the hole in the pen cap clip.
3. Tilt the pen cap slightly clockwise.



## DPP: Digital Pen Installation

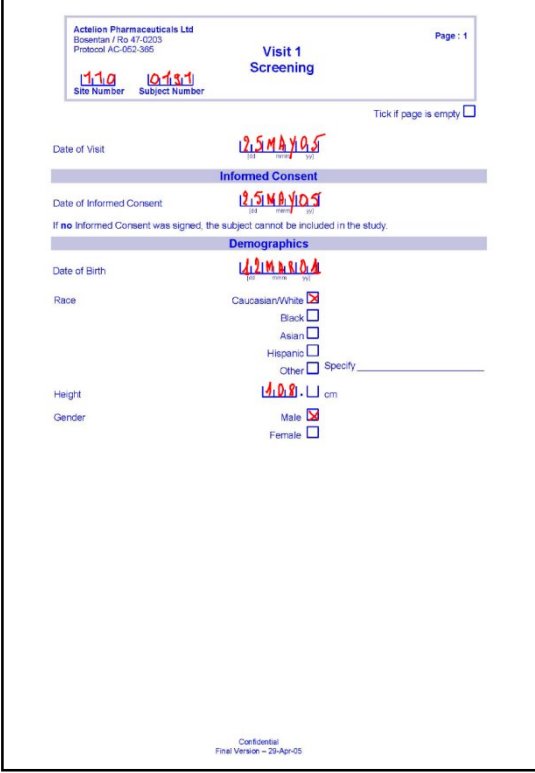
- Before the digital pen can be used it will have to be installed on your computer by the Regional Operation Manager / Regional Monitor during the initiation visit
- For installation of the digital pen software an '**Administrator**' access is required. Very often the hospital networks do not allow the installation of individual software, therefore the IT department within the hospital should be involved at an early stage, in order to allow the installation of the DPP software

## DPP: How Does the DPP work?



The investigator completes the CRF page with the Digital Pen (blue ink), which captures handwritten information

**Pen in the cradle**



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Bosentan / Ro 47-0203  
Protocol AC-062-386

Page : 1

Visit 1  
Screening

Site Number: 110 Subject Number: 0131

Tick if page is empty ☐

Date of Visit: 02 MAY 05

**Informed Consent**

Date of Informed Consent: 02 MAY 05

If no Informed Consent was signed, the subject cannot be included in the study.

**Demographics**

Date of Birth: 01 JAN 04

Race: Caucasian/White ☒  
Black ☐  
Asian ☐  
Hispanic ☐  
Other ☐ Specify \_\_\_\_\_

Height: 1.68 m

Gender: Male ☒  
Female ☐

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## DPP: How does the DPP work (cont'd)

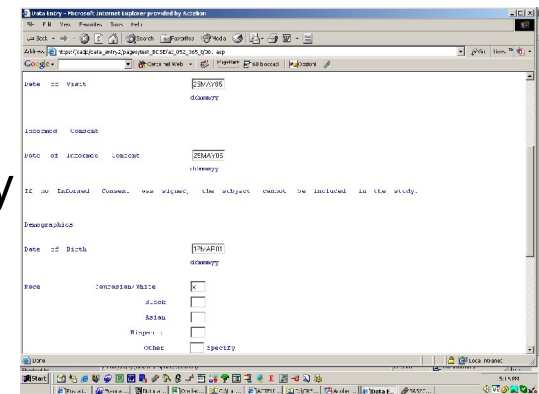
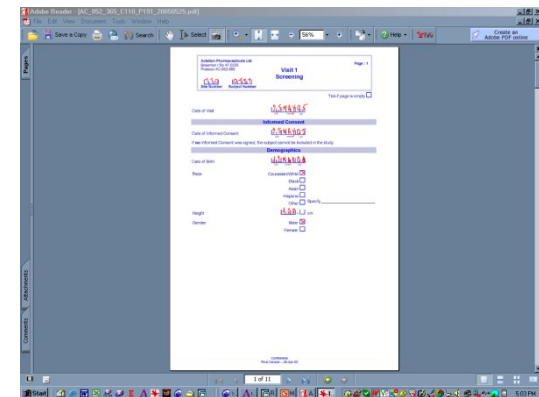
Information is transferred into a host system via USB → Data uploaded and **processed** automatically



Printed Output

CADP Data Entry

Images immediately available



## DPP: Advantages of the Digital Pen

- If CRFs are completed on an ongoing basis (i.e not the day before the monitoring visit) → instant access to the data **before the next site monitoring visit**
- Continuous resolution of issues with the aim to reduce queries and the time to database closure

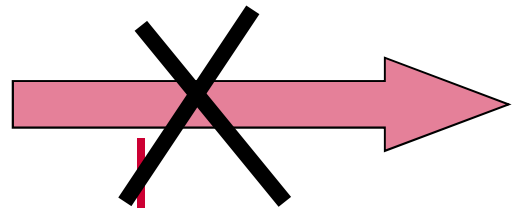
## DPP: Potential Problems

### 1. Writing on the CRF by mistake, with a normal pen



## DPP: Potential Problems (cont'd)

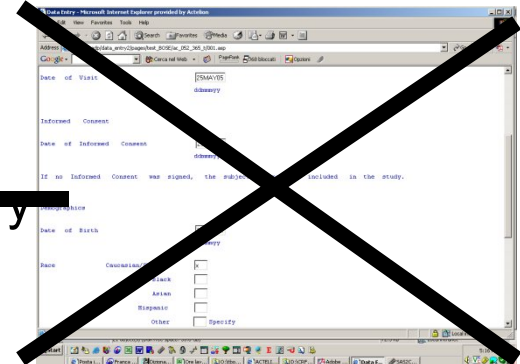
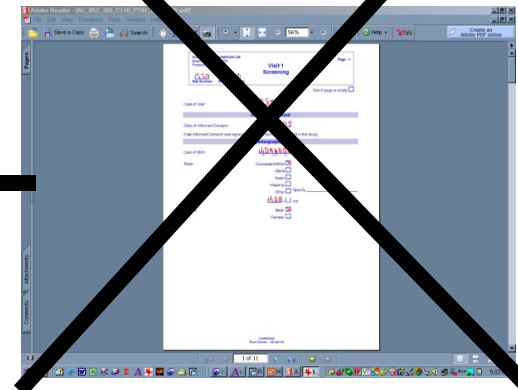
This will **destroy the unique CRF pattern** and the digital pen will no longer be able to identify the CRF data.  
**Data will not be transferred** → No data for the monitor to review before the monitoring visit → No data entry



Printed Output

CRF Data Entry

**Images immediately available**



## DPP: Potential Problems (cont'd)

2. With all IT based systems something can **fail / break / crash**

In any case, **no data is lost** because final data entry is based on the original paper version



## DPP: Summary

- Always use the **Digital pen**
- Complete the CRF after each subject visit on an **ongoing basis** -> Do not leave it until the day before the monitoring visit
- Place the pen in the cradle after completing the CRF to allow the upload of captured information
- Place the pen in the cradle when it's not being used
- **Never exchange** CRF pages between subjects as the CRF is unique for ONE subject only

**Your monitor will support you with the installation and with all questions you may have about the DPP**

## Query flow Agenda

- What type of queries?
- What is a QT1?
- What is a QT2?
- What is a QT3?
- What is the data/query flow?
- Summary

## Query Management: Different query types

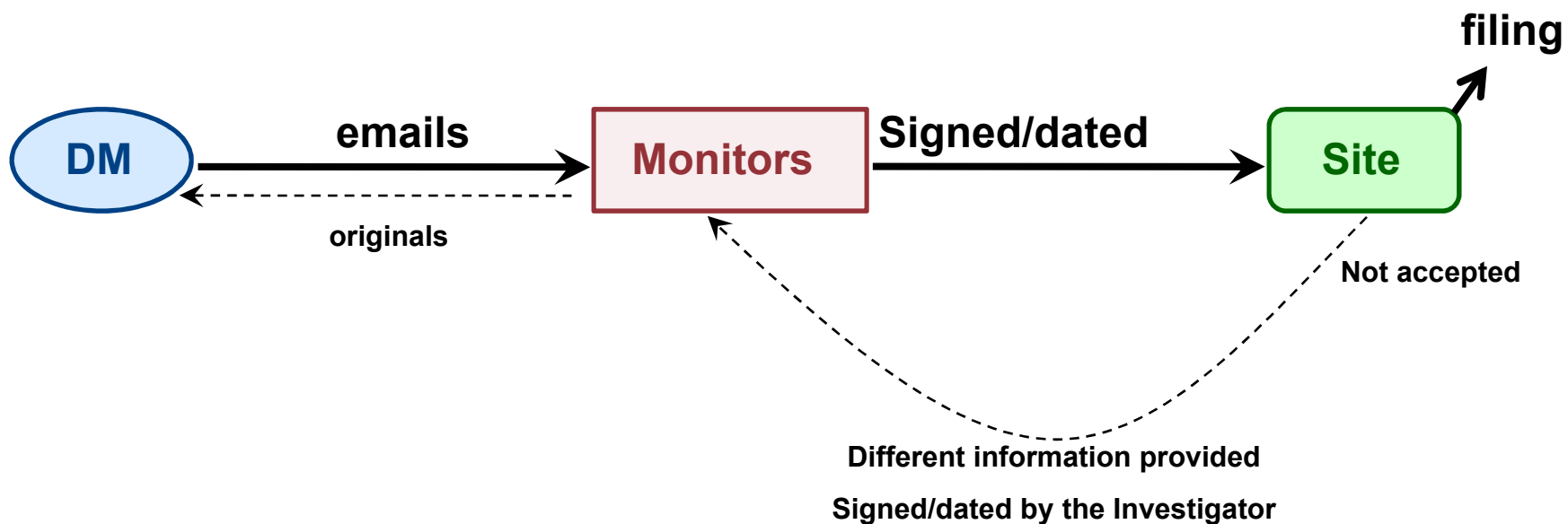
- **QT1**= Query Type 1 (self-evident)
- **QT2**= Query Type 2 (investigator)
- **QT3**= Query Type 3 (On-Site Queries/DCF)

## Query Management: Different query types (cont'd)

- A **QT1** addresses an issue that can be **resolved without impacting the integrity of the data** in the database, i.e self evident corrections made on DB by sponsor. Provided to the Investigator for information.
- A **QT2** query are associated to inconsistencies on the CRF page that need further clarification and **needs written confirmation (signature+ date) from the Investigator.**
- A **QT3** query addresses an on-site monitor query for CRF pages already sent to Actelion and data entered. **Needs written confirmation (signature+ date) from the Investigator.**

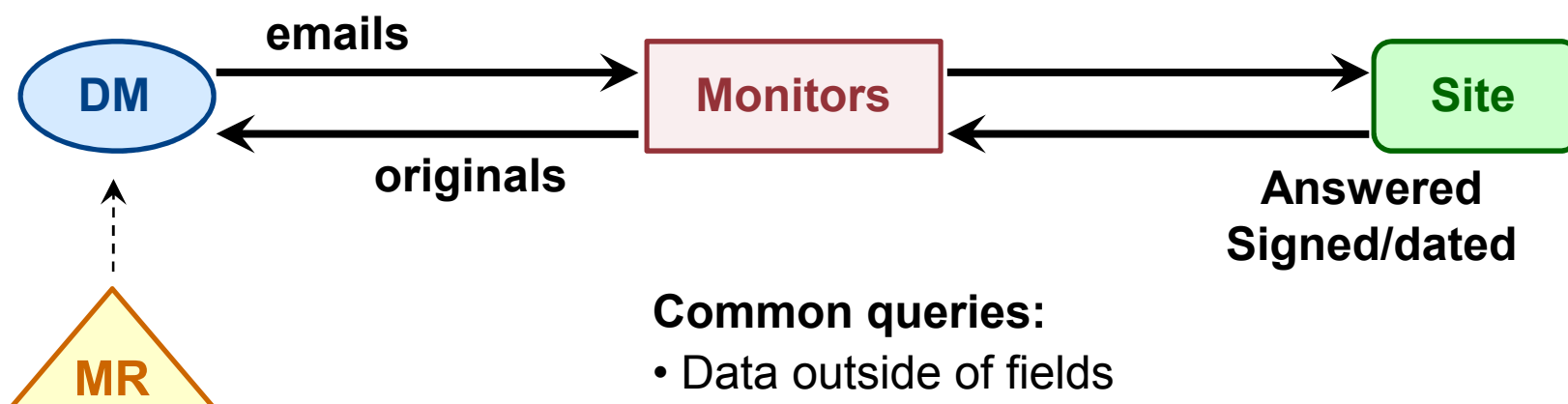
## Query Management: Query flow

**QT1**



## Query Management: Query flow (cont'd)

**QT2**

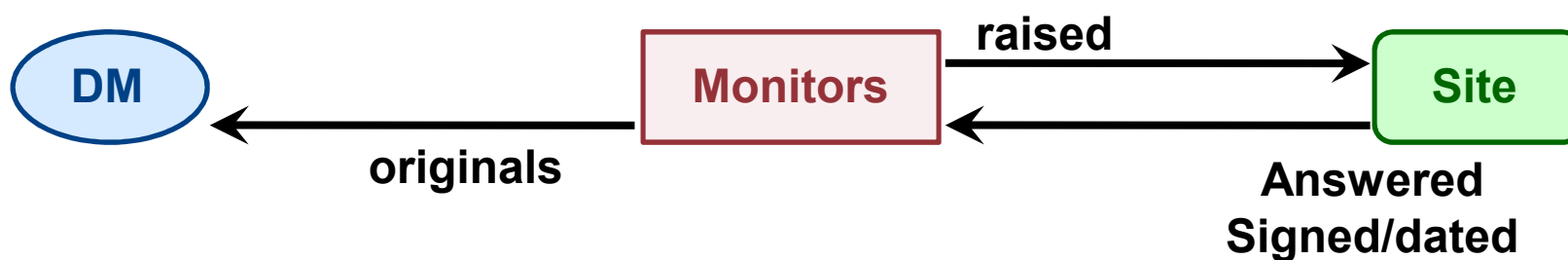


### Common queries:

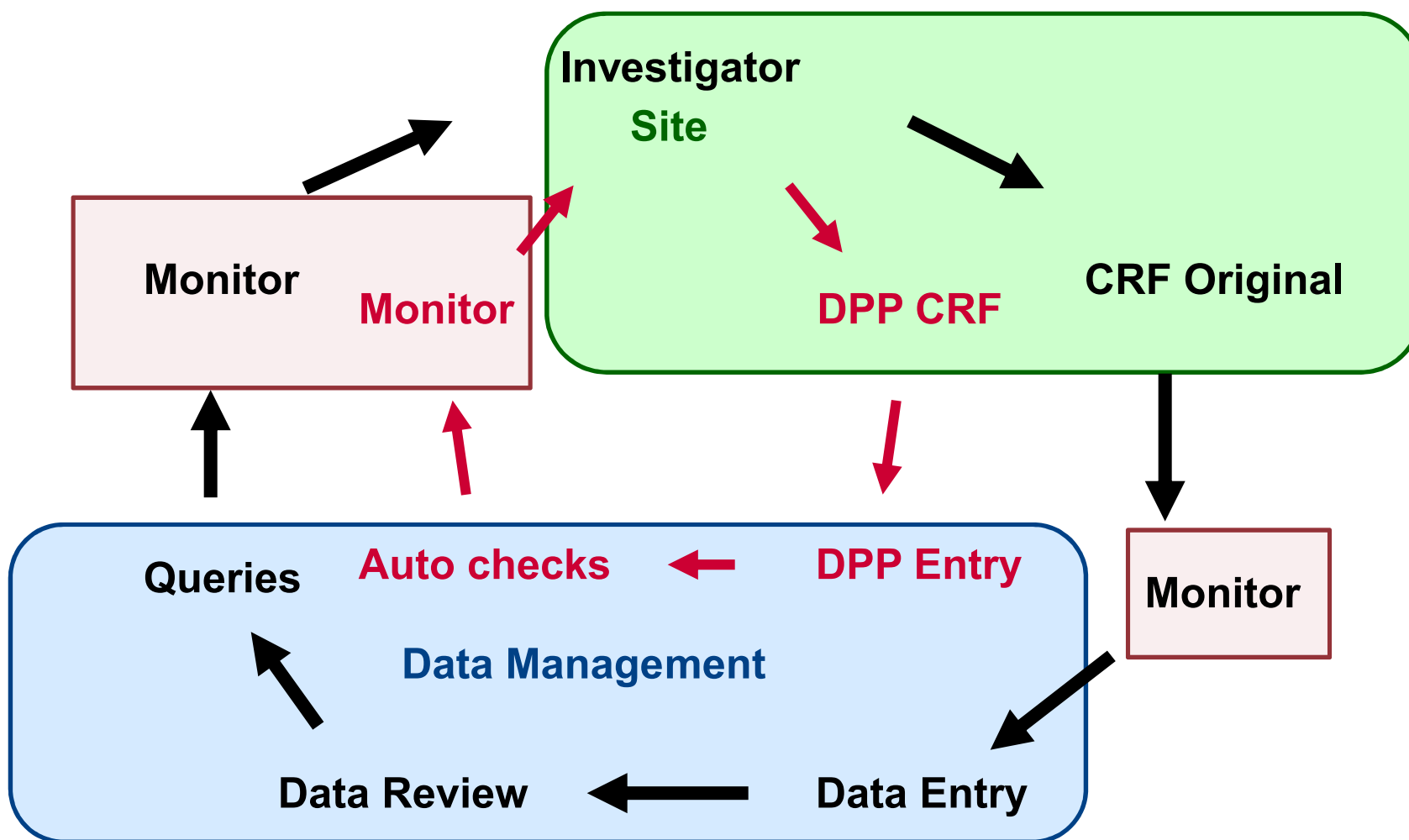
- Data outside of fields
- Corrections not initialled or dated
- Values out of ranges
- AEs onset dates before first study drug intake
- Coding issues

## Query Management: Query flow (cont'd)

**QT3**



## Data/Query Flow: summary





Thank You

Do you have any questions ?